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EXAMINER				
YABUT, DIANE D				
ART UNIT		PAPER NUMBER		
3734				
NOTIFICATION DATE		DELIVERY MODE		
06/23/2011		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/685,374

Applicant(s)

BONSIGNORE, CRAIG

Examiner

DIANE YABUT

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2011.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8-16, 18 and 19 is/are pending in the application.
4a) Of the above claim(s) 5, 6, 10-16, 18 and 19 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-4, 8-9 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-945)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

This action is in response to applicant's amendment received on 04/06/2011.

The examiner acknowledges the amendments made to the claims.

Claims 1-6, 8-16, and 18-19 are pending in this application. Claims 5-6, 10-16, and 18-19 are withdrawn from consideration.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-4 and 8-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 recites "the graft extension and the main trunk being formed as a continuous, one-piece, unitary structure having no seals." However, the main trunk has first and second stent-anchors that serve as seals: See page 5, paragraph 16: "Proximal and distal main trunk anchors 15, 16 serve to seal main trunk 20 to native vessel 10 proximally and distally to the incision 12 and graft extension 30." Also in paragraph 17 seals are on graft extension 30 in the form of internal graft anchor 41 and external graft anchor 42. Therefore it appears as though

the opposite is disclosed in the specification – that the main trunk and the graft extension do have seals.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-4 and 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Wisselink** (U.S. Patent No. **5,984,955**) in view of **Hartley** (U.S. Pub. No. **2004/0082990**).

Claims 1 and 3-4: In Figures 1a, 1f, and 2c **Wisselink** discloses a single flow channel main trunk **12-12a** having first and second ends, first and second stent-anchors **18** disposed completely within and covered by the main trunk (see col.7, lines 59-67), the first and second stent-anchors securing the first and second ends of the main trunk within a vessel, a graft extension configured as part of the main trunk and extending from the main trunk or being in fluid communication with the main trunk (as it is near **46** in Figure 2c), the graft extension and the main trunk being formed as a continuous, one-piece, unitary structure (it is noted that in the present application, a graft extension **30** extends from an incision in a main trunk **12** and are one-piece in the sense that they create a continuous, integral, unitary structure), a bypass graft **14** or **16** in fluid communication with the graft extension, wherein the graft extension and the bypass

graft have an overlapping region (see Figures 1b-1c), wherein the outside diameter of the graft extension is substantially equal to the inside diameter of the bypass graft (see Figures 2b-2c. col. 4, lines 42-67, col. 7, lines 39-67). Wisselink also discloses that the graft extension ("branch graft **16**") may extend from the main trunk having a branch graft opening **14** in an acute angle: small side branch vessels require "branch graft **16** be passable through such branch graft opening(s) **14** and into the smaller side branch vessel...at an angle of approximately 80-90 degrees, relative to the axis of the aorta" (col. 8, lines 15-27).

In Figure 2c Wisselink lacks the single flow channel main trunk having a first diameter above the graft extension and a second diameter below the graft extension, the first and second diameters being equal. However, Wisselink also discloses another configuration in the embodiment of Figures 1a-1f wherein the above limitation is met. The graft extension in this embodiment may be referred to as **40**, and forms a continuous, one-piece, unitary structure with the main trunk **12**. Also, although the embodiment in Figures 1a-1f and 2a-2c do not show coupling of first and second vessels that are not in communication at a juncture between the main trunk and the graft extension and wherein the graft extension is connected through an incision in the first vessel, the device of Wisselink is configured for connecting two vessels in this manner since it has a configuration with a main trunk and a branch graft extension.

Wisselink lacks an internal anchor and an external anchor, wherein the internal anchor is positioned within the graft extension and is configured to exert a chronic outwardly directed outward force and the external anchor is integral with or positioned

outside the bypass graft and is configured to exert a chronic inwardly directed force, the internal anchor and the external anchor cooperating to seal the graft extension and the bypass vessel, both the internal anchor and the external anchor being positioned concentrically in the overlap region to create a fluid tight seal between the graft extension and the bypass graft, although Wisselink does disclose a branch graft anchoring device (stent) **20** that anchors the graft extension to a vessel.

Hartley teach an overlap region comprising an internal anchor **68** positioned within a "proximal prosthesis portion" or graft extension **62** and being configured to exert a chronic outwardly directed outward force and an external anchor **72** being integral with or positioned outside a "distal prosthesis portion" or bypass graft **66** and being configured to exert a chronic inwardly directed force, the internal anchor and the external anchor cooperating to seal the graft extension and the bypass vessel, both the internal anchor and the external anchor being positioned concentrically in the overlap region to create a fluid tight seal between the graft extension and the bypass graft (Figure 7, paragraphs 58-59).

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the connection between the graft extension and the bypass graft in Wisselink by providing an internal anchor and an external anchor, as taught by Hartley, in order to provide a smooth region and effective seal between the two tubular portions or vessels (paragraph 59) and "advantageously" the internal anchor and external anchor are overlapped to provide this effective seal (see abstract).

Wisselink also do not disclose the graft extension and the main trunk "having no seals" in the figures since a fluid-tight seal is created between the graft extension **16** and the main trunk **12** as seen in Figures 1b-1c for example through the coupling of mechanical elements **46** and **44** to **40** and **42**. The recitation of "seals" is interpreted as referring to mechanical sealing elements that connect the graft extension to the main trunk, as in the present specification there appear to be no mechanical sealing elements that couple main trunk **12** to graft extension **30**, although one may consider the two to be sealed or coupled since they are in fluid communication with one another. Wisselink acknowledges alternative coupling between the graft extension **16** and the main trunk **12** that do not involve mechanical seals or "having no seals" as indicated in col. 9, lines 51-58: "electromagnetic, chemical" coupling means, for example.

Claim 2: Wisselink discloses said bypass graft comprising an artificial graft **16** or a donor vessel (col. 7, lines 39-67).

Claim 8: Wisselink discloses said first and second stent-anchors exerting an outward force to seal said main trunk in a main vessel (col. 7, lines 49-52).

Claim 9: Wisselink discloses said first and/or second stent-anchors comprising a plastically deformable material (col. 1, lines 52-67).

Response to Arguments

3. Applicant's arguments filed 4/06/2011 have been fully considered but they are not persuasive.

Applicant generally argues that Wisselink does not disclose the new limitations provided in the amendment as recited in claim 1, including (1) the graft extension not extending in an acute angle from the main trunk, (2) the graft extension being configured for connection to a second vessel not in communication with the first vessel at this juncture through an incision in the first vessel, or (3) the graft extension and the main trunk both forming a unitary structure having no seals. As mentioned above, the limitations are addressed, respectively, as follows: (1) Wisselink also discloses that the graft extension ("branch graft **16**") may extend from the main trunk having a branch graft opening **14** in an acute angle: small side branch vessels require "branch graft **16** be passable through such branch graft opening(s) **14** and into the smaller side branch vessel...at an angle of approximately 80-90 degrees, relative to the axis of the aorta" (col. 8, lines 15-27). (2) Also, although the embodiment in Figures 1a-1f and 2a-2c do not show coupling of first and second vessels that are not in communication at a juncture between the main trunk and the graft extension and wherein the graft extension is connected through an incision in the first vessel, the device of Wisselink is configured for connecting two vessels in this manner since it has a configuration with a main trunk and a branch graft extension. (3) Wisselink also do not disclose the graft extension and the main trunk "having no seals" in the figures since a fluid-tight seal is created between the graft extension **16** and the main trunk **12** as seen in Figures 1b-1c for example through the coupling of mechanical elements **46** and **44** to **40** and **42**. The recitation of "seals" is interpreted as referring to mechanical sealing elements that connect the graft extension to the main trunk, as in the present specification there appear to be no

mechanical sealing elements that couple main trunk **12** to graft extension **30**, although one may consider the two to be sealed or coupled since they are in fluid communication with one another. Wisselink acknowledges alternative coupling between the graft extension **16** and the main trunk **12** that do not involve mechanical seals or "having no seals" as indicated in col. 9, lines 51-58: "electromagnetic, chemical" coupling means, for example.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-5PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on (571) 272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. Y./
Examiner, Art Unit 3734

/Gary Jackson/
Supervisory Patent Examiner, Art Unit 3734